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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,334	01/23/2002	Anthony C. Aliberto	001/062 USA	3333

29554 7590 12/31/2002

ATTN: SARAH KIRKPATRICK, I.P. RIGHTS
ALSIUS CORPORATION
15770 LAGUNA CANYON ROAD, SUITE 150
IRVINE, CA 92618

EXAMINER

THISSELL, JEREMY

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,334

Applicant(s)

ALIBERTO ET AL.

Examiner

Jeremy T. Thissell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg '208 in view of Clifton (US 5,486,204).

Ginsburg teaches all the claimed subject matter including use of the cooling catheter during surgery (col. 2, line 51) except for specifically teaching that the surgery is on an aneurysm, and that the device is used to treat patients suffering from head trauma. Clifton teaches that it is well known to induce systemic hypothermia to treat patients undergoing aneurysm surgery (col. 1, line 36) or who are suffering from head trauma (title). It would have been obvious in view of Ginsburg's broad teaching that the device can be used during surgery, to use it during aneurysm surgery as taught by Clifton in order to lower the body's requirement for oxygen.

Also, induced hypothermia has long been used to treat head trauma, as demonstrated by Clifton who uses cooling blankets (col. 4, lines 40-41). Ginsburg teaches that his method of using a cooling catheter is superior to older simpler methods such as cooling blankets (col. 1, lines 63-64). It would have been obvious to one of

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ordinary skill in the art to use a superior cooling technique as taught by Ginsburg to treat head trauma which is well-known to be treated by hypothermia as taught by Clifton.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dato (US 3,425,419) in view of Williamson, IV et al (Us 5,716,370).

Dato teaches use of a heat-exchange cooling catheter to cool a patient during heart valve surgery (col. 1, lines 32-35). However, the surgery is "open-heart surgery," which involves a thoracotomy (or opening the chest cavity to expose the heart). However, Dato's patent dates back to 1965. In the last 37 years, the art of heart surgery has progressed to such a degree that many procedures are now performed in a minimally invasive manner (without the thoracotomy). Williamson teaches that it is well-known to perform valve surgery, in a minimally invasive manner, while inducing hypothermia (col. 2, line 6; col. 8, line 28). In view of the progression of heart surgery, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the heat exchange device of Dato to provide hypothermia during a minimally invasive heart surgery as taught by Williamson in order to efficiently provide a global state of hypothermia without the drawbacks of other cooling methods as discussed by Dato (col. 1, lines 36+).

Response to Arguments

Applicant's arguments with respect to claim 5 have been considered but are moot in view of the new ground(s) of rejection.

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Applicant's arguments filed 4 October 2002 have been fully considered but they are not persuasive.

With respect to claim 8, Applicant argued that there would be little likelihood for success of the combination of Ginsburg with Clifton because the Ginsburg device inadequate because "[t]he heat exchange applications for which Ginsburg was evidently designed, require only cooling in relatively small body vessels" Applicant alleges that therefore, Ginsburg would not be capable of inducing the "profound" hypothermia set forth in Clifton. However, the examiner points to column 4, lines 21+ of Ginsburg, which state *inter alia*, "Preferably, the catheter will be inserted into a relatively large blood vessel" Ginsburg was designed to control a patient's core body temperature by conducting a heat exchange in a relatively large blood vessel, and is capable of circulating a cooling fluid cold enough to make the actual heat exchange surface of the catheter as low as 0° C. The Examiner takes the position that this device can be reasonably expected to produce the profound hypothermia of 8-10° C in Clifton.

Conclusion

This action is being made NON-FINAL in view of new grounds of rejection.

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
December 28, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700